



## CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

July 2, 2007

### **H.R. 2900** **Food and Drug Administration Amendments of 2007**

*As approved by the House Committee on Energy and Commerce  
on June 21, 2007*

#### **SUMMARY**

H.R. 2900 would authorize the collection and spending of user fees by the Food and Drug Administration (FDA) for certain activities to expedite the marketing approval of prescription drugs and medical devices and to regulate prescription drugs after they enter the market. Such fees would be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts.

The bill also would establish a surveillance system to monitor and assess the safety profile of drugs on the market, enhance FDA's authority to regulate marketed drugs, expand federal databases that track information on certain clinical trials, and reauthorize and modify programs that evaluate the use of drugs and devices by children. The legislation would authorize funds to extend FDA's grant program for orphan products, conduct post-marketing surveillance of medical devices, establish programs to accelerate innovation and improve the evaluation of medical products, and promote the security of drugs distributed in the United States.

On balance, CBO estimates that implementing H.R. 2900 would have net discretionary costs of \$728 million over the 2008-2012 period. Enacting the bill would increase direct spending by \$7 million over the 2009-2012 period and by \$200 million over the 2009-2017 period. Finally, we estimate that enacting H.R. 2900 would decrease net federal revenues by \$1 million over the next five years and by \$41 million over the 10 years through 2017.

H.R. 2900 contains both intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). The bill would preempt any state or local law that requires manufacturers of medical devices or drugs to register clinical trials and related information in a database, but the net costs of that mandate would be minimal and far below the threshold established in UMRA (\$66 million in 2007, adjusted annually for inflation).

The most costly of the bill's private-sector mandates would be the requirement that manufacturers of prescription drugs and medical devices pay fees to the FDA. The direct cost of the fees would exceed the annual threshold specified in UMRA (\$131 million in 2007, adjusted annually for inflation).

## **ESTIMATED COST TO THE FEDERAL GOVERNMENT**

H.R. 2900 would affect discretionary and direct spending, as well as revenues. (See Tables 1 and 2 at the end of this estimate). The costs of this legislation fall primarily within budget functions 550 (health) and 570 (Medicare). It would also affect budget functions 370 (commerce and housing credit), 700 (veterans benefits and services), and 750 (administration of justice).

### **Spending Subject to Appropriation**

Assuming appropriation action consistent with the bill, CBO estimates that implementing H.R. 2900 would reduce net discretionary outlays by \$100 million in 2008, primarily because the spending of fees lags somewhat behind their collection. CBO estimates that gross spending in subsequent years would exceed the amounts collected from user fees (because some of that spending under the bill would not be offset by fees), and that the net cost of implementing the bill would amount to \$728 million over the 2008-2012 period, assuming the appropriation of the necessary amounts (see Table 1).

Because a significant portion of the cost of FDA activities would be offset by user fees, the largest component of the net discretionary cost of implementing H.R. 2900 would be an estimated \$432 million in spending over the 2008-2012 period mostly for pediatric research conducted by the National Institutes of Health. It is unclear how a provision in the bill (in section 103) would be implemented. The provision would require FDA to reduce annual assessments for user fees dedicated to drug safety activities based, in part, on certain levels of funds appropriated for the "process of human drug review." Given that uncertainty, our estimate reflects the full (unadjusted) collections of user fees authorized under the bill plus any funding provided by additional authorizations of appropriations.

### **Direct Spending**

H.R. 2900 also would extend the authority for FDA to administer an incentive program that grants market exclusivity to manufacturers that voluntarily conduct studies on the use of drugs in certain pediatric populations, the so-called "pediatric exclusivity program." The bill

would require that affected periods of existing market exclusivity be extended by an additional six months if the manufacturer meets specified requirements. (During such period of pediatric exclusivity, FDA could not permit another manufacturer to market a version of the drug.)

Extending market exclusivity for certain prescription drugs by six months would delay the entry of lower-priced generic versions of those drugs, which would affect both direct spending and federal revenues. Because delaying the availability of lower-priced generic drugs would increase spending on pharmaceutical benefits by federal health programs, CBO estimates that direct spending for Medicare, Medicaid, the Federal Employees Health Benefits (FEHB) program, and the TRICARE for Life program would increase by an estimated \$7 million over the 2009-2012 period and \$200 million over the 2009-2017 period (see Table 2). (CBO estimates that the market exclusivity provisions would increase discretionary spending by the FEHB program, Department of Veterans Affairs, Department of Defense, and other federal health benefits programs by about \$2 million over the 2009-2012 period. Those effects are included under "Provisions Affecting Pediatric Populations" in Table 1.)

## **Revenues**

H.R. 2900 would affect revenues in two ways. First, it would make certain violations of new requirements under the bill subject to civil money penalties; collections of such penalties are classified as federal revenues. Second, higher spending for prescription drugs would increase the cost of premiums for private health insurance. Higher premiums, in turn, would result in more of an employee's compensation being received in the form of nontaxable employer-paid premiums, and less in the form of taxable wages. As a result of this shift, federal income and payroll tax revenues would decline. CBO estimates that the proposal would reduce net federal revenues by \$1 million over the 2009-2012 period and \$41 million over the 2009-2017 period (see Table 2). Social Security payroll taxes, which are off-budget, would account for \$13 million of that total.

## **ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS**

H.R. 2900 would preempt any state or local law that requires manufacturers of medical devices or drugs to register clinical trials and related information in a database. That preemption would be an intergovernmental mandate as defined in the Unfunded Mandates Reform Act because it would limit the application of state and local law. While a number of states have considered legislation in recent years to establish such requirements, only a few have enacted them. In some cases, states have established fees that are tied to the registration

requirements. While those states would lose a small amount of fee revenues as a result of the preemption, costs of state regulatory responsibilities also would decline. Consequently, CBO estimates that the net costs to comply with the mandate would be minimal and far below the threshold established in UMRA (\$66 million in 2007, as adjusted for inflation).

Spending by states for Medicaid would increase by an additional \$35 million over the 2009-2017 period because of the provision in the bill that would delay entrance into the market of some generic drugs. Because states have flexibility in that program to adjust their financial and programmatic responsibilities, such additional spending would not result from an intergovernmental mandate.

## **ESTIMATED IMPACT ON THE PRIVATE SECTOR**

The bill would place a number of requirements on the manufacturers of prescription drugs and medical devices that would be private-sector mandates as defined in UMRA. The most costly of those mandates would be the requirement that those entities pay fees to the FDA. CBO estimates that the direct cost of those fees alone would exceed the annual threshold specified in UMRA (\$131 million in 2007, adjusted annually for inflation) in each of the five years that the mandates would be effective.

In addition to the fees on manufacturers of prescription drugs and medical devices under titles I and II, the bill contains other private-sector mandates that would impose additional but smaller costs. Title IV would renew FDA's authority to require that manufacturers undertake certain studies of the safety and efficacy of their drugs in pediatric populations. Title V would renew the Secretary's ability to award brand-name drug manufacturers six months of market exclusivity for the completion of FDA-requested pediatric studies. (The exclusivity period would effectively be a mandate on generic drug manufacturers because they would not be allowed to enter the market during that period.) Title VIII would require that manufacturers submit information about clinical trials to FDA. Title IX would enhance FDA's authority to regulate drugs by requiring that drug manufacturers submit a risk evaluation and mitigation strategy if the Secretary determines that such a strategy is necessary to protect the public's health.

## **PREVIOUS CBO ESTIMATE**

On April 27, 2007, CBO transmitted a cost estimate for S. 1082, the Prescription Drug User Fee Amendments of 2007, as reported by the Senate Committee on Health, Education, Labor, and Pensions. Many of the provisions contained in H.R. 2900 as ordered reported by the House Committee on Energy and Commerce are contained in S. 1082. The differences between the two bill are reflected in CBO's two estimates.

H.R. 2900 differs from S. 1082 in a number of ways. For example, H.R. 2900 would provide six months of exclusivity to all drugs granted pediatric exclusivity under the program; S. 1082 would limit the pediatric exclusivity period to three months for certain "blockbuster" drugs. H.R. 2900 would also allow FDA to require that firms submit television advertisements to FDA for review prior to distribution and to make certain violations related to direct-to-consumer advertising subject to civil monetary penalties. S. 1082 does not contain a similar provision.

In addition, the bills would authorize different levels of additional user fee collections for activities related to drug safety while specifying different adjustment mechanisms for assessing such fees in a given year. H.R. 2900 would authorize \$25 million a year through 2012 to establish a surveillance system for marketed drugs compared with annual authorizations of \$30 million under S. 1082.

H.R. 2900 also would authorize \$25 million annually through 2012 to carry out activities related to risk evaluation and management strategies and for initiatives by several federal agencies to improve the security of drugs distributed in the United States. The bill would authorize \$30 million annually over the 2008-2012 period to extend FDA's grant program for orphan products and additional funding for other activities.

In total, CBO's estimate of net discretionary spending for H.R. 2900 is \$181 million higher than for S. 1082 over the 2008-2012 period. Estimates of direct spending and revenues are also different for the two bills. Over the 2009-2017 period, CBO estimates that direct spending under H.R. 2900 would be \$50 million higher and total net revenue losses would be \$9 million higher than for S. 1082 as reported by the Senate Committee on Health, Education, Labor, and Pensions.

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**TABLE 1. ESTIMATED IMPACT OF H.R. 2900 ON DISCRETIONARY SPENDING**

	By Fiscal Year, in Millions of Dollars				
	2008	2009	2010	2011	2012
<b>CHANGES IN SPENDING SUBJECT TO APPROPRIATION</b>					
Collections from User Fees					
Prescription Drug Fees	-463	-541	-626	-717	-886
Advertising Fees	-13	-8	-10	-10	-11
Medical Device Fees	-48	-53	-57	-62	-67
Total, Estimated Authorization Level	-524	-602	-693	-789	-964
Total, Estimated Outlays	-524	-602	-693	-789	-964
Spending of User Fees					
Prescription Drug Fees	463	541	626	717	886
Advertising Fees	13	8	10	10	11
Medical Device Fees	48	53	57	62	67
Total, Estimated Authorization Level	524	602	693	789	964
Total, Estimated Outlays	345	594	682	776	878
Net Changes in User Fees					
Estimated Authorization Level	0	0	0	0	0
Estimated Outlays	-179	-8	-11	-13	-86
Other Proposed Changes:					
Risk Evaluation and Mitigation Strategies					
Authorization Level	80	80	80	80	80
Estimated Outlays	56	79	84	81	81
Provisions Affecting Pediatric Populations					
Program for Pediatric Research					
Estimated Authorization Level	0	75	150	200	225
Estimated Outlays	0	19	79	144	190
Other Provisions					
Estimated Authorization Level	14	19	24	25	26
Estimated Outlays	11	19	23	25	26
Other Provisions <sup>a</sup>					
Estimated Authorization Level	15	21	25	27	28
Estimated Outlays	12	20	22	26	28
Total Changes					
Estimated Authorization Level	109	195	279	332	359
Estimated Outlays	-100	129	197	263	239

a. Amounts primarily reflect costs for the Food and Drug Administration and the National Institutes of Health of expanding federal efforts to collect information on clinical trials, establishing partnerships with private entities to foster the innovation and safety of medical products, and enhancing federal oversight of medical devices to assess their safety after market entry.

**TABLE 2. CHANGES IN DIRECT SPENDING AND REVENUES UNDER H.R. 2900**

	By Fiscal Year, in Millions of Dollars										2008-	2008-
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2012	2017
<b>CHANGES IN DIRECT SPENDING</b>												
Estimated Budget Authority	0	*	*	1	5	11	19	29	53	83	7	200
Estimated Outlays	0	*	*	1	5	11	19	29	53	83	7	200
<b>CHANGES IN REVENUES</b>												
Estimated Revenues												
On-budget	0	*	*	*	-1	-2	-3	-4	-7	-11	-1	-28
Off-budget	<u>0</u>	<u>*</u>	<u>*</u>	<u>*</u>	<u>*</u>	<u>-1</u>	<u>-1</u>	<u>-2</u>	<u>-4</u>	<u>-5</u>	<u>*</u>	<u>-13</u>
Total	0	*	*	*	-1	-3	-4	-6	-11	-16	-1	-41

Note: \* = less than \$500,000; components may not sum to totals because of rounding.